



Washington State
Health Care Authority

Health Technology Assessment Updates

Josh Morse, HTA Program Director
WA – Health Care Authority
May 18, 2018



Washington State
Health Care Authority

Today's agenda

1. Surgery for symptoms of lumbar radiculopathy
2. Pharmacogenetic testing of patients being treated with anticoagulants



Meeting reminders

- Meeting is being recorded
- A transcript of proceedings will be made available on HTA website: www.hca.wa.gov/hta/meetings-and-materials
- When participating in discussions:
 - ❖ State your name; and
 - ❖ Use the microphone
- To provide public comment during today's meeting:
 - ❖ Sign-up at the table outside this meeting room



HTA program background

- The Health Technology Assessment (HTA) program is administered under the Washington State Health Care Authority (HCA)
- 2006 legislation designed HTA program to use evidence reports and a panel of clinicians to make coverage decisions for certain medical procedures and tests based on evidence of:
 - ❖ Safety
 - ❖ Efficacy/ Effectiveness
 - ❖ Cost-effectiveness



HTA program background

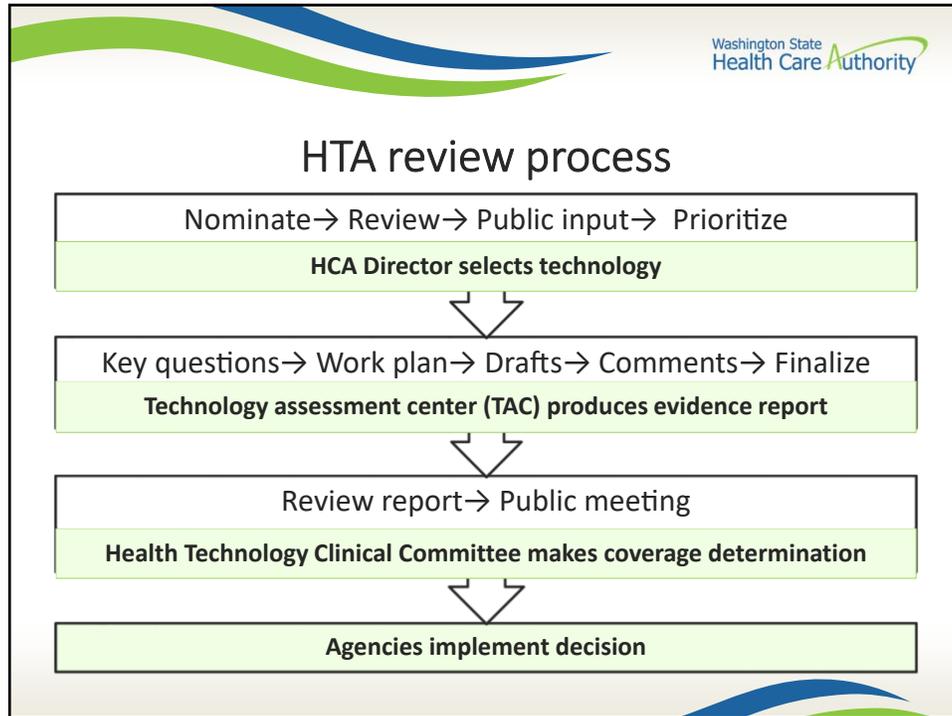
- Multiple state agencies participate to identify topics and implement policy decisions:
 - ❖ **Health Care Authority**
 - Uniform Medical Plan
 - Medicaid
 - ❖ **Labor and Industries**
 - ❖ **Department of Corrections**
- Agencies implement determinations of the HTA program within their existing statutory framework.



HTA purpose

Ensure medical treatments, devices and services paid for with state health care dollars are safe and proven to work.

- Provide resources for state agencies purchasing health care
- Develop scientific, evidence-based reports on medical devices, procedures, and tests.
- Facilitate an independent clinical committee of health care practitioners who determine which medical devices, procedures, or tests meet safety, efficacy, and cost tests.





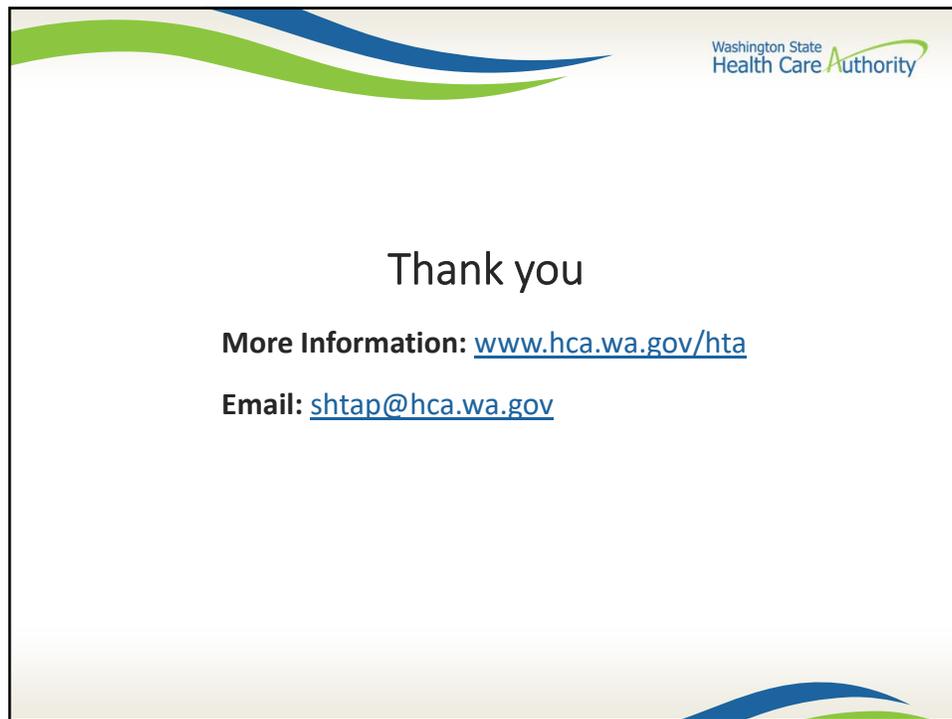
2019 committee calendar

- ❖ **January 18, 2019**
Sacroiliac joint fusion
Peripheral nerve ablation
- ❖ **March 15, 2019**
Wearable defibrillators
- ❖ **May 17, 2019**
Proton beam therapy – re-review
- ❖ **July 11, 2019**
Webinar



To participate...

- Visit the HTA Web site:
www.hca.wa.gov/about-hca/health-technology-assessment
- Sign up to receive HTA program notifications via email
- Provide comment on:
 - Proposed topics
 - Key questions
 - Draft & final reports
 - Draft decisions
- Attend HTCC public meetings/ present comments directly to the clinical committee.
- Nominate health technologies for review.



Health Technology Clinical Committee

Date: March 16, 2018

Time: 8:00 am – 5:00 pm

Location: SeaTac Conference Center, SeaTac, WA

Adopted:

Meeting materials and transcript are available on the [HTA website](#)

Draft HTCC Minutes

Members present: John Bramhall, MD, PhD, Gregory Brown, MD, PhD; Laurie Mischley, ND, PhD, MPH, Sheila Rege, MD MPH; Seth Schwartz, MD, MPH; Mika Sinanan, MD, PhD; Kevin Walsh, MD; Tony Yen, MD

Clinical experts: Nancy E. Davidson, MD

HTCC Formal Action

- 1. Call to order:** Dr. Brown, chair, called the meeting to order; members present constituted a quorum.
- 2. HTA program updates:** Josh Morse, HTA program director, presented an overview of the development and purpose of the HTA program. He also provided information regarding the 2018 committee calendar.
- 3. January 19, 2018 meeting minutes:** Draft minutes reviewed; no changes or updates suggested. Motion made to approve January 19, 2018 minutes as written, seconded. Committee voted to accept the minutes.
Action: Eight committee members approved the January 19, 2018 meeting minutes.
- 4. Genomic microarray testing and whole exome sequencing - Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. No comments were received on the draft decision. No changes were made to the draft.
Action: Eight committee members voted to approve the Genomic microarray testing and whole exome sequencing finding and decision.
- 5. Continuous Glucose Monitoring - Draft findings and decision:** Chair referred members to the draft findings and decision and called for further discussion. Changes were suggested for clarification. Under limitations of coverage, first paragraph – an “or” was placed after each of the bullet points. Under the first paragraph, third bullet point: “Unable” replaced “Inability”.
Three comments were received on the draft decision. The committee reviewed and discussed the comments. No additional changes were made to the draft.
Action: Eight committee members voted to approve the Continuous glucose monitoring finding and decision.

DRAFT

6. Gene expression profile testing of cancer tissue

Clinical expert: The chair introduced Nancy E. Davidson, MD, Senior Vice President and Director, Clinical Research Division, Fred Hutchinson Cancer Research Center; President and Executive Director, Seattle Cancer Care Alliance; Head, Department of Medicine, Division of Medical Oncology, University of Washington School of Medicine.

Agency utilization and outcomes: Emily Transue, MD, MHA, Associate Medical Director, Health Care Authority, presented the state agency perspective on for *Gene expression profile testing of cancer tissue*. The full presentation is published with the [March 16 meeting materials](#).

Scheduled and open public comments: The chair called for public comments. Comments were provided by:

- Devki Saraiya , MS, CGC, Myriad Genetic Laboratories
- Karen Heller, MS, CGC, Myriad Genetic Laboratories

Public presentation materials provided are published with the [March 16, meeting materials](#).

Vendor report / HTCC question and answer:

Valerie J. King, MD, MPH, OHSU/Center for Evidence-based Policy presented the evidence review for *Gene expression profile testing of cancer tissue*. The full presentation is published with the [March 16 meeting materials](#).

HTCC coverage vote and formal action:

Committee decision

Based on the deliberations of key health outcomes the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and state agency utilization information. The committee decided that the current evidence on gene expression profile testing of cancer tissue is sufficient to make a determination on this topic. The committee discussed and voted on the evidence for use of gene expression profile testing of cancer tissue. The committee considered the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Based on these findings, the committee voted to cover with conditions gene expression profile testing of breast and prostate cancer tissue.

Separately, the committee voted to not cover gene expression profile testing of cancer tissue for colon cancer and multiple myeloma.

	Not covered	Covered under certain conditions	Covered unconditionally
Breast cancer	1	7	0
Prostate cancer	1	7	0
Colon cancer	7	1	0
Multiple myeloma	8	0	0

DRAFT

Discussion

The committee reviewed and discussed the available studies of Gene expression profile testing of cancer tissue. Details of study design, inclusion criteria, outcomes, technology used and other factors affecting study quality were discussed. A majority of committee members found the evidence sufficient to determine that select use of gene expression profile testing of cancer tissue could impact treatment decisions.

Limitations

N/A

Action

The committee checked for availability of a Medicare national coverage decision (NCD). Medicare does not have an NCD on gene profile expression testing for breast, prostate, or colon cancers or multiple myeloma. The committee discussed clinical guidelines identified for gene expression profile testing of cancer tissue from the following organizations:

- American Society of Clinical Oncology (ASCO) *Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women with Early-Stage Invasive Breast Cancer*, (2016).
- The American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and American Society of Clinical Oncology, *Molecular Biomarkers in Colon Cancer*, (2017).
- European Group on Tumor Markers (EGTM) *Use of biomarkers in breast cancer*, (2017).
- European Group on Tumor Markers (EGTM) *Use of biomarkers in multiple myeloma*, (2017).
- European Group on Tumor Markers (EGTM) *Use of biomarkers in colon cancer*, (2016).
- European Society for Medical Oncology (ESMO) *Clinical Practice Guidelines Breast Cancer*, (2015).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: *Breast Cancer*, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: *Prostate Cancer*, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer: *Multiple Myeloma*, (2017).
- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer by Site: *Colon Cancer*, (2017).
- NICE National Institute for Health and Care Excellence, *Breast Cancer*, (2013).

The committee chair directed HTA staff to prepare a findings and decision document on use of gene expression profile testing of cancer tissue for public comment; followed by consideration for final approval at the next public meeting.

7. 2018 bylaws

The chair presented suggested updates to the current HTCC bylaws in order to:

- Remain consistent with current WACs (updated 2016);
- Enhance readability,
 - Bylaw topic headings were reordered; and
- Guarantee consistency between topic areas and the new laws
 - Vetted by the Attorney General's Office and in-house HCA legal staff.

Chair referred members to the draft bylaws and called for discussion. A suggested change under the heading of "Committee Membership and Terms, Appointment", paragraph 1: The reference to total length of committee membership, WAC 182.55.025, be presented in full written format.

Action: Eight committee members voted to approve the 2018 bylaws as amended.

8. Meeting adjourned.

Health Technology Clinical Committee Authority:

Washington State's legislature believes it is important to use a science-based, clinician-centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority (HCA), through its Health Technology Assessment (HTA) program, to engage in an evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and that takes public input at all stages.

Pursuant to RCW, 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State HTCC determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases its decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Director.

FINAL Key questions and background

Pharmacogenetic testing for patients being treated with anticoagulants

Background

Anticoagulant drugs, commonly known as blood thinners, are used for patients with conditions such as atrial fibrillation, deep venous thrombosis, or orthopedic surgery to prevent stroke, pulmonary embolism, or other complications from having a blood clot.¹ Warfarin, approved for use in the U.S. in 1954, is the most commonly prescribed oral anticoagulant, although use of direct oral anticoagulants (DOACs) is increasing.² When prescribing anticoagulants, the risk of thrombosis from the underlying condition needs to be weighed against the risk of bleeding from anticoagulation.³ Clinical decisions about which of these agents to use depend on the underlying indication for anticoagulation and other considerations such as the patient's creatinine clearance (a measure of renal function), other medications used, and history of serious bleeding. Achieving effective anticoagulation can require time, laboratory testing, and dose adjustments, particularly for warfarin.⁴ For example, diet, comorbidities, and interactions with other medications can lead to wide variation in warfarin dose requirements.⁴ Genetic variations are known to change patient response to various medications, and efforts to personalize therapy according to genetic differences have gained momentum.¹ This report will examine the clinical usefulness of genetic tests to guide initiation or dosage adjustments for oral anticoagulant drugs.

Policy context

There are a growing number of genetic tests and panels of genetic tests designed to inform decisions on the selection and dosage of oral anticoagulant medications. Potential benefits of these tests are more appropriate treatment decisions and better patient outcomes, including avoiding treatment-related side effects. This topic was selected for a health technology assessment because of low concerns for the safety of these tests, high concerns for efficacy, and medium/high concerns for cost.

This evidence review will help to inform Washington's independent Health Technology Clinical Committee as the committee determines coverage regarding selected genetic tests for patients with an indication for use of oral anticoagulant medications.

Proposed scope

Population: Adults and children initiating or changing dosage of oral anticoagulant medications

Interventions: Genetic testing to inform the selection or dosage of oral anticoagulant medications

Comparators: Usual care without genetic testing

Outcomes:

- Patient-oriented clinical outcomes (e.g., death, stroke, time in therapeutic range, overanticoagulation, bleeding, quality of life as measured by validated instruments)
- Consequences of treatment decisions (including decisions by prescribers or patients to use, not use, or continue use of specific medications) on response to treatment and adverse effects as a result of treatment
- Direct harms, such as consequences of inaccurate test results
- Cost-effectiveness and other economic outcomes

Time period for literature search: 2007 to the present

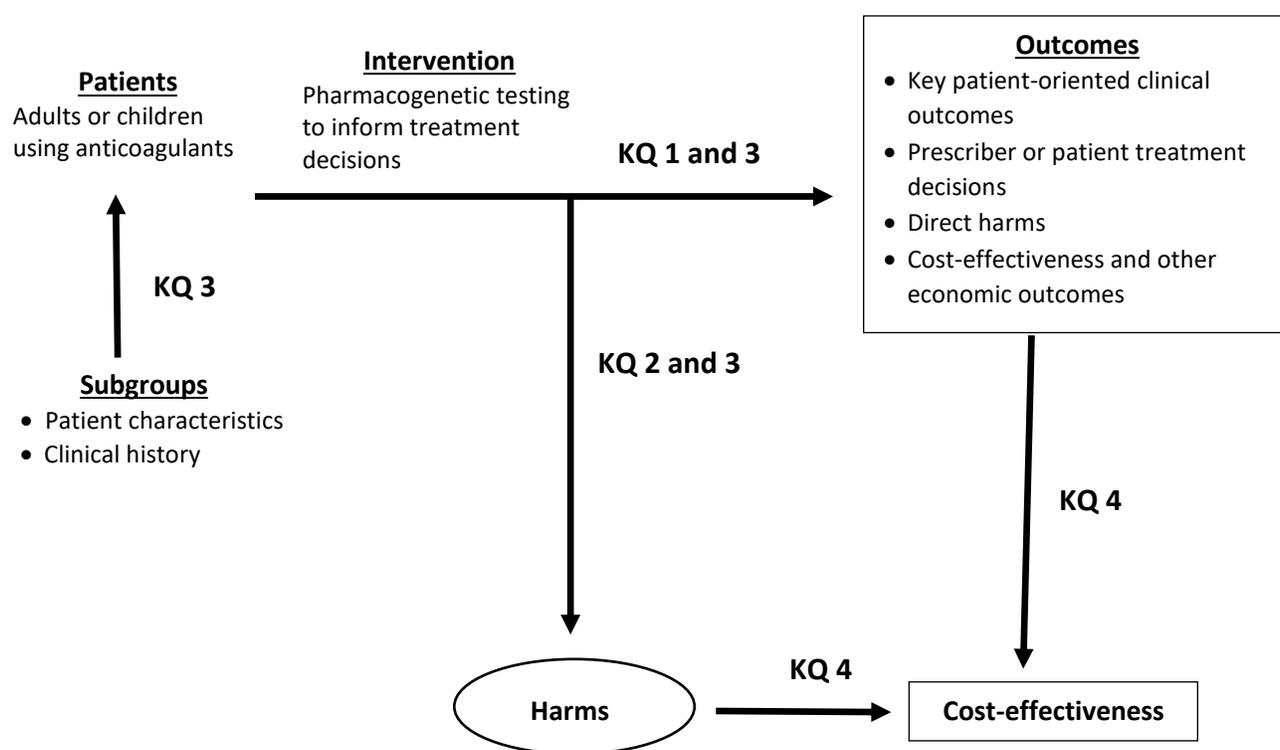
Key questions

1. Effectiveness: What is the clinical utility of genetic testing to inform treatment decisions for patients being treated with anticoagulants?
 - a. Do treatment decisions guided by genetic testing result in clinically meaningful improvements in important patient outcomes (e.g., death and stroke) or reductions in adverse events (e.g., bleeding) compared with usual care without genetic testing?
 - b. Does genetic testing to inform the selection or dose of medications change the drug or dosage selected by prescribers or patients compared with usual care without genetic testing?
2. Harms: What direct harms are associated with conducting genetic testing when it is used to inform the selection or dosage of oral anticoagulant medication?
3. Special populations: Compared with usual care without genetic testing, do important patient outcomes or harms after genetic testing vary by:
 - a. Patient characteristics (e.g., age, sex, race/ethnicity)?
 - b. Clinical history (e.g., medical comorbidities, underlying condition requiring anticoagulation, severity of illness, concurrent medication use, whether treatment decision is initial or subsequent)?
4. What are the cost-effectiveness and other economic outcomes of genetic testing used to inform the selection or dosage of oral anticoagulant medication?

Eligible studies

Randomized controlled trials (RCTs) and good-quality systematic reviews (with or without meta-analyses) of RCTs that assess listed clinical utility outcomes will be considered for Key Questions 1, 2, and 3. Methodologically robust cost-effectiveness studies and other prospective comparative economic evaluations, along with good-quality systematic reviews of these types of studies, will be considered for Key Question 4. If multiple systematic reviews and/or meta-analyses are available, then the one(s) that are most recent, comprehensive, robust, and applicable will be selected for inclusion. Studies will be required to be published in English and applicable to the U.S. setting.

Analytic framework



The analytic framework below will guide the selection, synthesis, and interpretation of available evidence.

References

1. Shi C, Yan W, Wang G, Wang F, Li Q, Lin N. Pharmacogenetics-based versus conventional dosing of warfarin: a meta-analysis of randomized controlled trials. *PLoS One*. 2015;10(12):e0144511.
2. Harter K, Levine M, Henderson SO. Anticoagulation drug therapy: a review. *The Western Journal of Emergency Medicine*. 2015;16(1):11-17.

3. Michigan Anticoagulation Quality Improvement Initiative. Anticoagulation toolkit. 2017; http://anticoagulationtoolkit.org/sites/default/files/toolkit_pdfs/toolkitfull.pdf
4. Emery JD. Pharmacogenomic testing and warfarin: what evidence has the GIFT trial provided? *JAMA*. 2017;318(12):1110-1112.

Public comment and response

See Draft key questions: Comment and response document published separately.

**Health Technology Clinical Committee
DRAFT Findings and Decision**

Topic: Gene expression profile testing of cancer tissue
Meeting date: March 16, 2018
Final adoption:

Meeting materials are available on the HTA website.

Number and coverage topic:

20180316A - Gene expression profile testing of cancer tissue

HTCC coverage determination:

Gene expression profile testing of breast cancer tissue is a **covered benefit with conditions**.

Gene expression profile testing of prostate cancer tissue is a **covered benefit with conditions**.

Gene expression profile testing of multiple myeloma is **not a covered benefit**.

Gene expression profile testing of colon cancer tissue is a **not covered benefit**.

HTCC reimbursement determination:

Limitations of coverage:

Gene expression profile (GEP) testing of breast and prostate cancer tissue is a covered benefit at a rate of one test per twelve (12) months per index cancer and when test results will impact treatment decisions.

Breast Cancer –

Oncotype DX, EndoPredict, Prosigna, and MammaPrint tests are covered for early stage 1 or 2 cancer.

- Estrogen receptor positive and HER2-NEU negative
- Lymph node negative or 1-3 lymph node(s) positive

Mammostrat and *BCI* tests are covered only for women with stage 1 or 2 cancer deciding about hormone therapy.

Prostate Cancer –

Oncotype DX and *Prolaris* are covered during early stage disease. *Decipher* is covered for men deciding between active surveillance and adjuvant radiotherapy after radical prostatectomy.

Non-covered indicators: N/A

Agency contact information:

Agency	Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-200-1004
Washington State Medicaid	1-800-562-3022

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- NCCN National Comprehensive Cancer Network Guidelines for Treatment of Cancer: Multiple Myeloma, (2017).
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Gene expression profile testing of cancer tissue

Draft findings and decision
Timeline, overview and comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Gene expression profile testing of cancer tissue.

Timeline

Phase	Date	Public Comment Days
Technology recommendations published	February 26, 2016	
Public comments	February 26, to March 10, 2016	14
Selected technologies published	April 18, 2016	
Public comments	April 19, to May 18, 2016	30
Draft key questions published	October 6, 2017	
Public comments	October 6, to 20, 2017	15
Final key questions published	November 28, 2017	
Draft report published	January 4, 2018	
Public comments	January 4, to February 2, 2018	30
Final report published	February 21, 2018	
Public meeting	March 16, 2018	
Draft findings & decision published	March 28, 2018	
Public comments	March 27, to April 9, 2018	14
		103

Overview

Category	Comment Period <i>March 27, to April 9, 2018</i>	Cited Evidence
Patient, relative, and citizen	0	0
Legislator and public official	0	0
Health care professional	0	0
Industry & manufacturer	1	1
Professional society & advocacy organization	0	0
Total	1	1

Comments

	Respondents	Representing	Cited Evidence
<input type="checkbox"/>	1. Karen Heller, MS, CGC	Myriad Genetics, Inc	Yes

Comments submitted by:
Karen Heller, MS, CGC
Medical Policy Manager
Myriad Genetic Laboratories
320 Wakara Way
Salt Lake City, Utah 84108
kheller@myriad.com
Tel: 214-789-5014

April 6th, 2018

Dear members of the Health Technology Clinical Committee,

We respectfully submit the enclosed comments on the DRAFT Findings and Decision for 20180316A, Gene expression profile testing of cancer tissue.

1) Prostate cancer

We support the Committee's recommendation to cover gene expression profile testing for prostate cancer, and respectfully suggest the following change for Prolaris and Oncotype DX:

- Change "early stage disease" to "low risk or favorable intermediate risk disease"

The term "early stage disease" may be confusing in the case of prostate cancer. Urologists generally categorize early prostate cancer as being low, intermediate or high risk, based on PSA, Gleason score and clinical stage. We provide the suggestion above in order for Washington Medicaid policy to be consistent with current NCCN guidelines¹ and the Medicare LCDs,^{2,3} which outline the patient types for whom data support improved outcomes from the use of these tests. Patients with low risk or favorable intermediate risk disease are potential candidates for active surveillance as well as interventional therapies, and the gene expression assays are suggested to provide additional risk discrimination to determine the appropriate treatment path for the individual patients.

2) Breast cancer

We support the Committee's decision to cover gene expression profile testing of breast cancer tissue, as these tests are used routinely in clinical practice to determine which individuals with early breast cancer have a sufficiently low chance of distant recurrence that they can safely forgo adjuvant therapy. In particular, we support the Committee's decision to include coverage for EndoPredict, which has been shown in comparative studies to perform at least as well as Oncotype DX, the current market-leading test.

A 2016 publication by Buus⁴ compared the prognostic ability of EndoPredict (EPclin) and Oncotype (RS) using archived samples from the prospective ATAC trial. Based upon the long-term outcome data from the trial, the hazard ratio for Oncotype was calculated to be 2.73 (95% CI 1.91-3.89, P<.001) and for EndoPredict it was 5.99 (95% CI 3.94-9.11, P<.001), reflecting EndoPredict's stronger ability to separate low and high risk patients. The EndoPredict result includes a continuous score as well as a bimodal classification of low or high risk.

More recently, Sestak⁵ compared several breast cancer gene expression assays using the same ATAC cohort. EndoPredict's prognostic ability compared favorably to the other assays, with calculated C-indices of 0.765 and 0.671 for node-negative and node-positive patients respectively.

The 2016 ASCO evidence review⁶ (performed prior to publication of the above two studies) concluded that EndoPredict has evidence of clinical utility, and the test is currently broadly covered by Medicare, most commercial payers (including Aetna, Humana, United, Anthem and almost all Blues plans including Premera and Regence) as well as numerous Medicaid plans (including current Washington policy with expedited pre-authorization status).

Thank you for the opportunity to provide these comments.

REFERENCES

1. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: prostate cancer-version 2.2017. 2017; https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
2. MoIDX-CDD: Prolaris Prostate Cancer Genomic Assay (L36350), effective October 15, 2015. Available at www.cms.gov/medicare-coverage-database/
3. MoIDX: Prolaris Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease (L37082), effective September 25, 2017. Available at www.cms.gov/medicare-coverage-database/
4. Buus R, Sestak I, Kronenwett R, et al. Comparison of EndoPredict and EPclin With Oncotype DX Recurrence Score for Prediction of Risk of Distant Recurrence After Endocrine Therapy. *J Natl Cancer Inst*. 2016 Jul 10;108(11). pii: djw149. doi: 10.1093/jnci/djw149. Print 2016 Nov.
5. Sestak I, Buus R, Cuzick J, et al. Comparison of the Performance of 6 Prognostic Signatures for Estrogen Receptor–Positive Breast Cancer. A Secondary Analysis of a Randomized Clinical Trial. *JAMA Oncol*. Published online February 15, 2018. doi:10.1001/jamaoncol.2017.5524.
6. Harris LN, Ismaila N, McShane LM, et al; American Society of Clinical Oncology. Use of Biomarkers to Guide Decisions on Adjuvant Systemic Therapy for Women With Early-Stage Invasive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline. *J Clin Oncol*. 2016 Apr 1;34(10):1134-50.